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REMARKS OF

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BEFORE THE

EBERSTADT, FLEMING GENERIC DRUG CONFERENCE

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Much will be written about the Congress that convened on Tuesday, January 6, 1987. It is the historic 100th Congress of the United States.

For those of us in and out of the Congress who care about public health and health policy, the 100th Congress is an opportunity to renew our commitment to solving our nation's most pressing health problems:

- 35 million Americans who have no form of health insurance;
- The AIDS epidemic and the millions of lives that hang in the balance;
- Health care costs, and particularly those costs not covered by insurance like nursing homes and drugs, that continue to race ahead notwithstanding record low inflation;
- A rapidly aging population that will leave the elderly of

the 21st century with overwhelming new health care needs that we are not prepared to meet.

This small list constitutes the most difficult of the matters that must be addressed. There are many more. The task ahead is large, but I enter the 100th Congress with a great deal of hope.

I hope for some major and some minor improvements in our public health and health care financing programs -- improvements that many of us have been pressing for throughout the Reagan Administration. I temper my hope, however, with hard reality.

The budget deficit is still with us, influencing every health policy decision we make. Budget cutting mania produces short-sighted savings. We make cuts in reimbursement rates for hospitals, doctors and pharmacists without full recognition of the potential long-run damage to the quality and availability of care. Next year's deficit reduction target of $108 billion will confound our efforts to care for the uninsured, to meet the treatment costs of AIDS victims, and to be ready for nursing home care in the year 2000.

The other stark reality is that the Administration attacks even the proposals of its own health experts -- like Secretary Bowen's catastrophic care suggestion.

In lieu of constructive proposals, OMB requires strict Administration adherence to unacceptable, but familiar, attacks on

current programs:

- o Cap the federal contribution to the Medicaid program and leave new and predictable health care costs to be borne totally by the states.

- o Raise Medicare premiums and eliminate virtually all increases in payment rates for providers of health care.

The Congress has rejected these proposals before, and the Administration knows that. This exhibits once more the leading strategy of the Administration budget makers -- construct unacceptable and unworkable budgets and legislation and then leave the Congress to clean up the numbers and the programs.

Many are predicting that the 100th Congress will simply repeat the budget battles of the last six years. While I, too, fear a repetition of past budget battles, I find an increasing awareness that some health care problems can and must be addressed.

PHARMACEUTICALS AND HEALTH CARE

In the field of pharmaceuticals and health care, there were successes and failures in the 99th Congress and there will be much activity in the 100th.

AIDS

The previous Congress took an important new step in the war on AIDS. We provided $50 million to develop new drugs to treat the deadly disease. With these new funds, NIH will test candidate drugs and design as-yet-undiscovered ones.

VACCINE COMPENSATION

The 99th Congress recognized the needs of the few children who suffer from immunizations so that the many can be disease free. We created a childhood vaccine compensation program.

We take our childhood vaccines for granted. They are public health miracles. In 1952, there were 57,000 cases of paralytic polio, last year there were 4.

Our confidence is so great that elementary schools require vaccines for entry. That is sound public policy. Unfortunately, vaccines are not completely safe; so some children are hurt in the line of public duty. Every year there are serious reactions, including mental retardation, permanent disability and death.

These children have no place to file their grievances or turn for care. To make matters worse, the drug companies that make vaccines are nervous. Progress toward new and potentially safer vaccines has slowed.

The compensation fund is a generous no-fault system to pay for the medical, rehabilitation, and education costs of those children who are injured. If the injury is particularly severe, the program would pay for lost earnings of the disabled child and for the pain and suffering that he or she endures. In turn, the child's ability to sue the manufacturer would be limited.

The compensation fund will be generated by an excise tax on the vaccines. Because the tax committees were bogged down with tax reform, the excise tax was not included in last year's bill. The tax will be considered this year. I am confident that with the new system in place, the Congress will pass the necessary excise tax.

Congress also created a "fast track" for new vaccines. Armed with $20 million, a Congressionally mandated vaccine "czar" at the Department of Health and Human Services will coordinate all government activity, including at FDA. Our goal is to expedite government and joint public-private initiatives in research, development, approval and procurement.

When President Reagan signed the law creating the vaccine compensation program, he voiced serious misgivings. He is concerned that we will have a new and expensive entitlement. In the face of such objections, I believe the American people will opt to help the few children who, like veterans of war, are injured doing their social duty.

DRUG EXPORT

The 99th Congress passed the long-debated "drug export" legislation. For years, U.S. drug companies have claimed that U.S. jobs are going overseas to make the drugs that Europe approves before we do. In May 1986, the Senate passed an export bill that went far beyond any legitimate claim for relief. The recently passed law has a much more narrow scope.

A U.S. company that has a drug in human clinical trials will be allowed to export that drug from the U.S., prior to its approval here. Export is limited to a statutory list of industrialized countries with drug approval systems that protect their citizens from unsafe products.

The law does not permit export to developing countries. And we did address the often-repeated allegations of mislabeling and dumping by U.S. companies in Third World countries. The Office of Technology Assessment will conduct a two-year study to determine if U.S. companies are properly labeling the drug products they sell overseas.

MEDICAID

The 99th Congress extended the benefits of the Medicaid program to several needy groups. There were many pregnant women, children under the age of five, and disabled and elderly citizens who were below the poverty level, but still not eligible for coverage. In allowing states to include these people, we extended to them physician and hospital

care as well as the broad array of prescription drugs that Medicaid pays for.

GENERIC DRUGS

That is what the 99th Congress did. What we did not do is often as important. The absence of further Congressional action on the 1984 generic drug bill is a clear signal that we like the results.

Nine of the top ten selling brand name drugs are now available as generics. Hundreds of newly-approved generic drugs are creating the only kind of war consumers want -- price wars.

The President predicted a billion dollars of consumer savings over a decade. That is a conservative estimate. The 1986 Industrial Outlook of the Commerce Department goes further and says that the generic industry will show an increase in sales of more than a billion dollars on 1986 alone, and that by 1990 about 30 percent of all prescription drugs will be generics.

This is just the beginning of the impact of the 1984 law. As insurance companies, hospitals, and public programs become familiar with possible savings, many will begin to shift to generic products. Total acceptance by the public is inevitable.

Only the brand name companies hold out. They criticize generics with the 1980s sophisticated version of the 1960s diatribe against

unsafe and ineffective generics.

Their anti-generic campaign is carefully calculated to discourage generic use and boost corporate revenues. It may work in the short run, but I believe they underestimate the American people.

With time, the companies responsible for anti-generic activities will suffer. They cannot make generics in private while they lambast them in public. Their credibility and reputation are at stake.

PRESCRIPTION DRUG PRICES

In coordination with the anti-generic theme, brand name companies have also raised their prices at unprecedented rates. The public and the health care system are the losers from this double dose of corporate greed.

The elderly use 30 percent of the prescription drugs in the U.S., but Medicare does not pay for drugs. Moreover, nationwide data show that 80 percent of the drugs in the U.S. are bought without any insurance, leaving consumers with the full burden of increased costs.

And consumer costs have skyrocketed. At my Subcommittee's July 15, 1985 hearing, we documented the unprecedented rise. Between 1981 and June, 1985, the CPI increased 23%. During the same time, drug manufacturer wholesale prices rose 56%. Many of the top-selling drugs rose even faster.

These enormous increases continued in 1986. It is my understanding that double digit price increases were commonplace. My Subcommittee will be conducting another hearing on prices in March of this year.

If prices continue to skyrocket, I believe the fundamental balance of our patent system will be distorted. We award monopolies to innovators. But when the innovation is an essential drug, we cannot allow a private enterprise to price sick people out of the market.

The Canadian compulsory licensing system insures price competition long before the U.S. patent would expire. Their compulsory licensing system and other efforts to hold prices at reasonable levels must now be explored.

Brand name companies have not responded to new market pressures with good faith for the American people. At a time when much of the health care industry is under severe cost constraints, unprecedented price increases and an anti-generic campaign are a source of great concern.

GENERIC ANIMAL DRUGS

In 1986, Congress considered, but failed to pass legislation for generic animal drugs. The bill was modeled after the 1984 law. It would have created a generic approval system for animal drugs and

provided patent term restoration for brand name animal drugs. The bill failed in the Senate because the brand name companies insisted on special transition rules to protect drugs already on the market.

I expect similar legislation to be considered again in the 100th Congress.

100TH CONGRESS

There will be much legislation in the 100th Congress that this group will be interested in. I expect Congressman Dingell, who chairs the Committee on Energy and Commerce, to reintroduce his drug diversion bill. That important consumer legislation bogged down in an end-of-the-session dispute with the pharmaceutical companies over the control of free drug samples.

ORPHAN DRUGS

A number of problems with the Orphan Drug Act have been identified and must be addressed. We desparately need additional grant funds for research on drugs that companies will not sponsor.

We also must clarify who has the right to receive the seven years of market exclusivity. Under current law, when two companies simultaneously develop an orphan drug, the first company that is approved gets the right to market the drug and the second gets nothing. We must find a way to reward orphan drug development that does not

discourage independent and simultaneous work by a second company.

DRUG COVERAGE

One of the most important out-patient health benefits that is not covered by Medicare and not usually covered by private insurance is prescription drugs. My immediate concern is for the elderly who are but 11% of the population and yet consume 30% of the drugs.

Out-patient drug costs are the second highest out-of-pocket expense for the elderly -- behind nursing home care. For many who receive nothing but Social Security checks, the choice each month is between their medicine and their rent or food. Our sick elderly citizens deserve far more from us.

Medicare coverage for drugs could be quite expensive, especially by the standards of today's budget. But the failure to follow a doctor's prescription is a "medical catastrophy" just as the extended hospital stay that Medicare doesn't cover is a financial catastrophy. In fact, not taking the necessary drugs could produce the very catastrophic illness we all want to protect our seniors against.

I believe it is time we considered how to assure our elderly that essential drugs will always be available to them.

AIDS

Without question, the most urgent problem awaiting the 100th Congress is the AIDS Epidemic.

The Public Health Service estimates that within 5 years we may be paying $16 billion a year for AIDS medical care alone -- equal to about 25% of the entire Medicare budget. The National Academy of Sciences says this is a severe underestimate.

A sizable portion of these costs will be Federal costs, especially as private insurers redline those people who have been exposed.

But as best we can tell, there is no serious planning for how these costs will be borne by the Medicaid and Medicare programs. The Health Care Financing Administration is planning budgets as if the need for health services will be steady, not as if we are about to enter a period of greatly increased need for services.

MEDICAID REIMBURSEMENT FOR GENERICS

Many of you are probably familiar with the Medicaid Maximum Allowable Cost (MAC) program that we suspended in 1983. The MAC Program was Medicaid's way to limit reimbursement to pharmacists to the cost of generic drugs, when they were available.

The Department of Health and Human Services cited problems in setting fair reimbursement levels and minimal savings that made the program unimportant. I agreed in 1983, but the 1984 generic drug law

changed things.

The Department of Health and Human Serivces has yet to come forward with a new proposal. An Administration that proposes $70 billion in Medicare and Medicaid cuts in the next five years certainly should be expeditious in renewing the generic reimbursement program.

Further discussion is unnecessary. Further delay raises serious questions about the motivations of the Department of Healtn and Human Services. Are they protecting the brand name companies or the Federal government?

If new regulations are not immediately forthcoming, my legislation will be.

MEDICAL DEVICE REGULATION

I also intend to push ahead with my bill to reform medical device regulation. Current law demands far more than FDA's meager resources can deliver. It is time to set new priorities. It is time to focus FDA's attention on those matters with the greatest impact on consumer health and safety.

NURSING HOMES

And last, the time has come to refocus our regulation of nursing homes. The Institute of Medicine has just completed a two year

Administration-sponsored study of nursing home regulation. I intend to introduce legislation which reflects the study's findings.

For years we have attempted to protect nursing home residents by auditing their physical surroundings. A better approach is to focus on patient outcome.

New requirements, even if we eliminate some of the old, will cost money. I believe our elderly deserve nothing less than the assurance that their nursing home stay will improve their condition. If that takes more money, I am ready to spend it.

CLOSING

As you can see, the 100th Congress will be memorable for more than its number. Legislation will be coming fast and furious. For those interested in the health care marketplace it will be a decisive year for policy and practical economics.

Thank you.